

**REMARKS****A. Claim amendments**

Claims 1 and 3-16 were originally in the application. Claims 3, 8 and 16 were cancelled without prejudice or disclaimer and claims 1, 9, and 15 were amended to further clarify the invention. Support for the amendment of claims 1, 9 and 15 can be found in the application at paragraphs [0016] to [0018]. Claims 1, 4-7, and 9-15 are now pending in this application. No new matter has been introduced into the application as a result of the above amendment.

**B. Objections to the specification**

The Examiner had objected to the title and missing abstract. The specification has been amended to replace the title as suggested by the Examiner and to insert an abstract. Support for the abstract can be found in the original filed PCT application. No new matter has been introduced into the application as a result of the current amendment.

Withdrawal of the objections to the specification is in order and is respectfully requested.

**C. Objections to the claims**

The Examiner had objected to certain informalities in claims 1 and 13. In view of the present amendment, the Applicant submits that the objections are now moot.

Withdrawal of the objections to the claims is in order and is respectfully requested.

**D. Claim Rejections under 35 U.S.C. section 112, first paragraph (written description and scope)**

Claims 1 and 3-15 were rejected under 35 U.S.C. section 112, first paragraph, for allegedly containing subject matter not described in the specification and for scope. The Examiner's comments can be found in the Office action at pages 5-8 and are not repeated here. Applicants respectfully traverse the rejection and submit that in light of the present claim amendments, the rejections are now moot.

As amended, claim 1 and its dependent claims are drawn to a method for purifying and/or isolating filamentous bacteriophages using a metal ions containing membrane. Metal ions containing membrane are broadly described, in detail, at paragraphs [0015, [0026], [0029] and [0030], of the specification. Furthermore, the Examples describe purification of a bacteriophage using a representative metal ions containing membrane. Accordingly, an ordinary skilled artisan in light of the teachings will understand how to make and use the claimed invention using metal ions containing membranes.

Withdrawal of the 35 U.S.C. section 112, first paragraph, rejections of the aforementioned claims is in order and is respectfully requested.

**E. Claim Rejection under 35 U.S.C. section 103(a)**

Claims 1 and 3-15 stand rejected under 35 U.S.C. section 103(a) as being unpatentable over Sartobind membrane absorbers brochure-A("Sartobind") as evidenced by Fischer-Furhholz and Stevely (*Journal of Virology*, 1977, Vol. 22, pages 232-234)(“Stevely”) in view of Sartobind membrane absorbers brochure by Hirai (“Hirai”). The Examiner alleged that it would have been obvious to one of ordinary skill in the art to apply a solution comprising PrV virus particles because Hirai allegedly taught applying PrV onto Sartobind membrane absorbers with different binding functional groups. Furthermore, the Examiner alleged that it would have been obvious to one of ordinary skill in the art to subject a PrV viral solution to additional ion exchange or filtration as allegedly taught by Hirai because additional purification steps result in a more pure product after purification. The Examiner alleges that Sartorius (in Hirai reference) teaches Sartobind membrane absorbers in the purification and removal of viruses for biopharmaceutical processes and Fischer-Fruhholz also disclosed Sartobind membrane absorbers for clearance of endotoxins. As a whole, the Examiner believes that the claimed invention is *prima facie* obvious. The Applicants respectfully traverses this rejection.

Fischer-Fröhholz relates to metal chelate membranes (see page 5 of Fischer-Fröhholz) as well as the purification of alpha herpes viruses using a cation exchange membrane (see page 32 of Fischer- Fröhholz). However, Fischer- Fröhholz does not teach or suggest the use of a metal ions containing membranes for virus purification. Stevely is remote to the

invention and merely relates to isolation of viral DNA and electron microscopic examination of the DNA. Hirai relates to virus purification using ion exchange membranes, but nowhere does Hirai teach or suggest the use of metal ions containing membranes for virus purification. "Sartobind® Membrane Absorbers brochure-A" merely provides a general overview in respect to several types of membranes, including metal chelate membranes (see page 5 section entitled "Sartobind membrane types", of "Sartobind® Membrane Absorbers brochure-A") and several types of applications for such membranes, including virus purification (see page 6 entitled "Applications" of "Sartobind® Membrane Absorbers brochure-A"). However, "Sartobind® Membrane Absorbers brochure-A" nowhere described or suggested the use of metal ions containing membranes for use in virus purification. Therefore, none of the cited references, alone or in combination, teach or suggest the use of metal ions containing membranes in a method for purifying viruses. A person of ordinary skill in the art having knowledge of Fischer-Fröhholz, Stevely, Hirai and "Sartobind® Membrane Absorbers brochure-A" would not have been motivated by the combined teachings of the aforementioned references to make and use the claimed method with any expectation of success.

As discussed in the application, the use of metal ions containing membranes (also known as metal chelate membranes) for the purification of viruses results in a surprisingly high yield and a surprisingly high purity of the virus (see the specification at paragraphs [0022] and [0023]) as well as in a surprisingly large amount of purified material per surface unit of the membrane (see the specification at paragraph [0025], of the description). The unexpected advantages of the presently claimed method of the present invention are nowhere described or even suggested in any of Fischer-Fröhholz, Stevely, Hirai or "Sartobind® Membrane Absorbers brochure-A".

Accordingly, withdrawal of the 35 U.S.C. section 103(a) rejection of the claims based on Fischer- Fröhholz, Stevely, Hirai or "Sartobind® Membrane Absorbers brochure-A" is in order and is respectfully requested.

Prompt consideration and entry of this amendment prior to examination is respectfully requested. If there are any questions or comments regarding this Amendment or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,



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